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Regulatory Proposal PRO2016-04

Policy on Cancellations and Amendments Following Re-evaluation and Special Review

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1.0 Purpose

The purpose of this document is to communicate the policy, process, and criteria for establishing timelines associated with the cancellation of pesticide products or amendments to product uses, labels, or other conditions of registration following a re-evaluation or special review decision.

2.0 Policy and Legal Framework

Pesticides in Canada are regulated by the Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, to prevent unacceptable risks to people and the environment. Before pesticides are approved, an extensive body of data and information must be provided by the applicant, and a human health and environmental risk assessment, as well as an assessment of the product's value, must be conducted. In addition, because science evolves and new health and environmental standards are established, pesticides in Canada undergo periodic reviews to ensure they continue to meet modern health and environmental standards. These reviews assist in determining whether a product can continue to be registered for use in Canada.

The *Pest Control Products Act* contains provisions for these post-market reviews of registered pest control products, namely re-evaluations and special reviews. By law, the Minister must initiate a re-evaluation on a 15-year cycle based on the most recent major registration decision, and may initiate a re-evaluation in circumstances where there has been a change in information requirements or a change in the procedures used to evaluate risks or value since the pesticide was initially registered. A special review is initiated where there are reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable, or when an Organisation for Economic Co-operation and Development (OECD) member country prohibits all uses of an active ingredient for health or environmental reasons.

During a re-evaluation or special review, the Minister may amend or cancel the registration if a registrant fails to provide information required under the *Pest Control Products Act*, or if the Minister has reasonable grounds to believe that the amendment or cancellation is necessary to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle.

The *Pest Control Products Act* provides the authority to amend or cancel the registration of a pest control product when, after conducting the necessary scientific evaluations and consultations, the Minister does not consider the risks or value of the product to be acceptable. In these circumstances a phase-out period may be implemented as part of the decision, commensurate with the level of risk. When cancelling a product, continued possession, handling, storage, distribution and use of stocks may be allowed, subject to any conditions considered necessary to protect human health and the environment. A phase-out period may be extended if no suitable alternatives to the use of the pesticide exist, and a determination is made that the health and environmental risks and value of the product are considered acceptable until the effective date of the amendment or cancellation.

See Appendix II for relevant sections of the *Pest Control Products Act*.

3.0 Policy Statement

This policy is intended to improve transparency by clarifying expectations of the process, and associated time frames, when action is required to remove products from the market, change approved uses, or introduce amendments to labels or other conditions of registration. The time frames for regulatory actions consider primarily the level of risk to health and the environment, but may also consider other factors such as the availability of alternatives, and existing stock and disposal issues.

4.0 Scope

This policy applies to the cancellation of pesticide products or amendments to product uses, labels, and other conditions of registration during or following a re-evaluation or special review. This policy does not address voluntary amendments or discontinuations by the registrant.

5.0 Health and Environmental Considerations for determining cancellation and amendment time frames

5.1 Level of Concern

When establishing the implementation time frame for cancellation of a product, or amendment with new restrictions such as adding additional risk mitigation measures to the label or removal of certain product uses, the following aspects will be considered:

- Whether (i) the risks are imminent, or (ii) the conditions of use do not meet current standards for long-term health and/or environmental protection
- Potential magnitude of harm (i.e. seriousness and severity of the effect of concern, including reversibility)
- Likelihood of the effect occurring (i.e. whether a serious effect is likely to happen based on how the product is currently being used).

Other considerations include:

- The population exposed to the product (for example, trained pesticide applicators, the general public, bystanders, etc.)
- Information from post-market surveillance (for example, incident reports, poison control centre data, monitoring data) considered as part of the re-evaluation or special review

5.2 Suitable Alternatives

There are circumstances in which additional time may be required to ensure an orderly implementation of a decision. For example, additional time may be required to ensure that, where consistent with preventing unacceptable risks to people and the environment, the channels of trade or the marketplace are not disrupted unnecessarily. Implementation periods may be extended if no suitable alternatives to the use of the pesticide exist, and a determination is made that the health and environmental risks and value of the product are considered to be acceptable until the effective date of the amendment or cancellation.

The suitability of potential alternatives as replacements is determined by a number of factors, such as whether they can provide a reasonable level of control of the pest, the economic impact of the change, or whether the change would promote misuse of other products or practices.

6.0 Procedures

6.1 Immediate Health and/or Environmental Concerns

Based on PMRA's experience to date, immediate or expedited product recall or removal of uses would be required only under exceptional circumstances. Such circumstances would involve imminent risk, where there is a significant likelihood of serious and severe effects occurring, thereby elevating the need to take immediate action. These circumstances may also be substantiated by adverse effects reported in incident reports submitted to the PMRA. Approaches may include: expedited implementation of cancellations or amendments; requiring the registrant to immediately over-sticker the label on existing stocks with the required mitigation; or, in accordance with the *Pest Control Products Act*, immediate product recall. In such instances, appropriate measures and their corresponding implementation timelines would be determined upon consideration of factors such as the potential magnitude and likelihood of identified risks.

6.2 Standard Process

6.2.1 Product Cancellation

Product cancellations may be required due to failure to provide information required under the *Pest Control Products Act*. When the product does not meet modern standards for health and/or environmental protection, but the likelihood of potential effects is not considered to be immediate and severe, products will typically be phased-out in order to allow for a reasonable transition to a suitable alternative, or to minimize the potential risks associated with disposing of large quantities of existing product. The phase-out will occur according to the following schedule:

- One (1) year of sale by registrant from the date of re-evaluation or special review decision plus
- Once (1) year of sale by retailer from the last date of sale by registrant to exhaust market supplies plus
- One (1) year of permitted use from the last date of sale by retailer to exhaust the remaining product

In other words, the product will be unavailable for sale after two (2) years, followed by one (1) year of permitted use to exhaust existing stocks, for a total of three (3) years to remove the product from the marketplace.

Subsequent to the original decision, if at any point it is determined that there is a greater likelihood of an immediate or imminent health and/or environmental concern that could be severe in nature, expedited timelines will be determined on a case-by-case basis commensurate with the likelihood and severity of the risk. An immediate product recall may be required in such cases.

6.2.2 Amendments

When an amendment to a registration is determined to be necessary as a result of the product not meeting modern standards for health and/or environmental protection, such as the need for additional risk mitigation measures or the cancellation of certain uses, the following process applies:

- PMRA notifies registrants of the need to amend their product registrations and update product labels to reflect the required amendments. PMRA also confirms the required process and implementation time frames.
- Registrants submit a Category C amendment application after being notified and will have their applications reviewed within current PMRA performance standards (i.e. 37 calendar days for a completeness check, followed by 240 calendar days for review) to confirm that they reflect the required amendments.
- When the likelihood of potential effects are not considered to be immediate and severe, registrants will typically have up to two (2) years from the date of the decision to transition to selling product with the newly amended labels. Old labels can be exhausted through the channels of trade at the retail level and through use at the user level.

Subsequent to the original decision, if at any point it is determined that there is a greater likelihood of an immediate or imminent health and/or environmental concern that could be severe in nature, expedited timelines will be determined on a case-by-case basis commensurate with the likelihood and severity of the risk.

7.0 Extended Phase-Outs

Typically the phase-out period for cancellation of a product is three (3) years from decision date until the last date of permitted use, and the typical last date of sale by registrant following a label amendment is two (2) years. In response to the consultation period following a proposed decision, registrants or users may request extended implementation timelines, with evidence supporting a lack of suitable alternatives, and a rationale for the acceptability of risk during the requested extension period. Extended phase-out timelines of up to an additional two (2) years, for a total of five (5) years from decision date until the last date of permitted use, will be determined on a case-by-case basis.

8.0 Failure to Implement Required Changes

Failure to make the required changes to product labels and/or remove products from the marketplace when required to do so could result in measures taken in accordance with the *Pest Control Products Act*.

9.0 Implementation

This policy is in effect as of the date of the final regulatory directive.

Appendix I Definitions

Cancellation: the termination of a product registration as authorized or required by the *Pest Control Products Act* (s.20, s.21), for example, due to risks of concern or failure to provide required data.

Amendment: a change to the conditions of registration of a product as authorized or required by the *Pest Control Products Act* (s20, s.21). Changes can include additional risk mitigation measures, or cancellation of certain uses. When required by re-evaluation or special review these are primarily enacted by making changes to the approved product label, usually through a Category C submission.

Phase-Out: the time frame or schedule under which a cancellation or amendment is implemented.

Appendix II Legislative Authority

This Appendix lists the Sections of the *Pest Control Products Act* which are relevant to the amendment or cancellation of registration of pest control products in the context of a special review or re-evaluation.

Section 20

(1) The Minister may cancel or amend the registration of a pest control product if
   (*a*) the registrant fails to satisfy a requirement under subsection 16(3) or 18(1) or paragraph 19(1)(*a*).
   (*b*) in the course of a re-evaluation or special review, the Minister has reasonable grounds to believe that the cancellation or amendment is necessary to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle set out in subsection (2).

(2) Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation.

(3) The Minister may rescind any action taken under subsection (1) if the circumstances that prompted it cease to exist.

Section 21

(2) If the Minister does not consider that the health or environmental risks or value of a pest control product are acceptable, the Minister shall
   (*a*) amend the registration if the Minister considers that the health and environmental risks and value of the product would be acceptable after the amendment; or
   (*b*) cancel the registration.

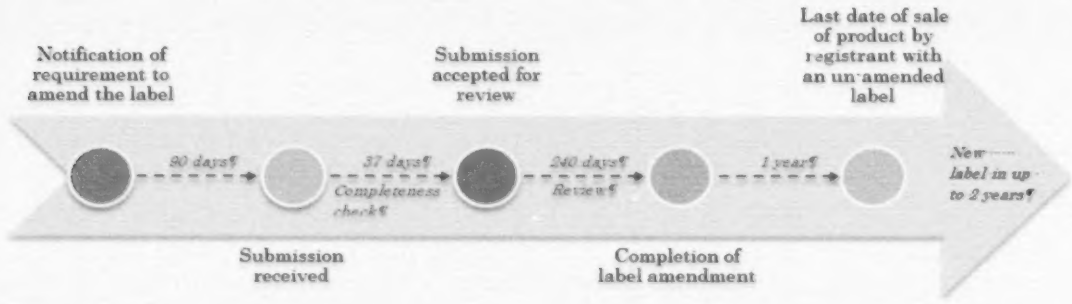
(3) The Minister may delay the effective date of the amendment or cancellation if
   (*a*) no suitable alternative to the use of the pest control product is available; and
   (*b*) the Minister considers that the health and environmental risks and value of the product are acceptable until the effective date of the amendment or cancellation.

(4) A delay is subject to any conditions that the Minister considers necessary for carrying out the purposes of this Act.

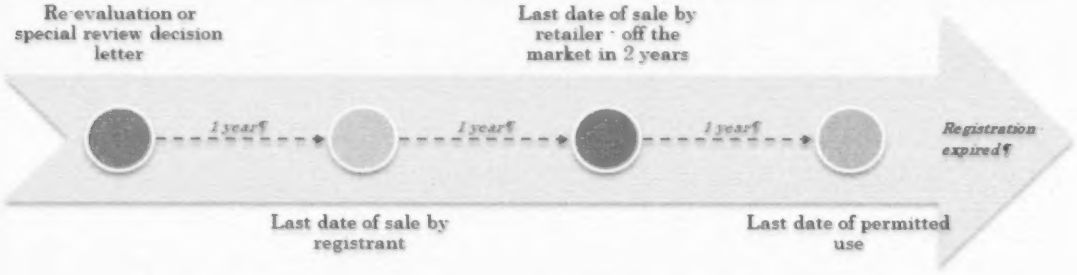
(5) When cancelling the registration of a pest control product under this section or any other provision of this Act, the Minister may
   (*a*) allow the continued possession, handling, storage, distribution and use of stocks of the product in Canada at the time of cancellation, subject to any conditions, including disposal procedures, that the Minister considers necessary for carrying out the purposes of this Act;
   (*b*) require the registrant to recall and dispose of the product in a manner specified by the Minister; or
   (*c*) seize and dispose of the product.

Appendix III Flowcharts

Amendments (required by the PMRA) – does not meet modern standards for health and/or environmental protection / no imminent issues – typically up to 2 years



Product Cancellation – does not meet modern standards for health and/or environmental protection / no imminent issues – typically up to 3 years


Re-evaluation or special review decision letter
Last date of sale by retailer - off the market in 2 years
1 year¶
1 year¶
1 year¶
Registration expired¶
Last date of sale by registrant
Last date of permitted use